K060684

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APR 24 2006

Submitter

Company:	3M ESPE AG
Street:	ESPE Platz
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Federal State:	Bavaria
Country:	Germany
Establishment Registration Number:	9611385
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Date:	March 09, 2006

Name of Device

Proprietary Name:	Adper™ Prompt™ Adper™ Prompt™ L-Pop™
Classification Name	Resin tooth bonding agent is designated at 21 C.F.R. §872.3200 as a Class II device.
Common Name:	Dental Adhesive

Predicate Devices:

Adper™ Prompt™, Adper™ Prompt™ L-Pop™ by 3M ESPE (K040857)

Adper™ Single Bond Plus by 3M ESPE (K962785)

Description for the Premarket Notification

Adper Prompt/Adper Prompt L-Pop is classified as Resin tooth bonding agent (21 C.F.R. §872.3200) because it is a device intended to be painted on the interior of a prepared cavity of a tooth to improve retention of restorative materials (compomer and composite restorative material). Additionally, Adper Prompt/Adper Prompt L-Pop can be used to seal dentinal tubules of exposed root surfaces to prevent from dentinal hypersensitivity.

Furthermore, as recent results show, Adper Prompt/Adper Prompt L-Pop is suited to bond RelyX™ Fiber Post, glassfiber-reinforced root canal posts by 3M ESPE, to light-curing composite core build-up materials. 3M ESPE submits this 510(k) premarket notification to seek clearance for this new indication for use.

Performance and comparative testing of Adper Prompt/Adper Prompt L-Pop has been carried out. The results suggest that Adper Prompt/Adper Prompt L-Pop is a suitable agent for bonding between RelyX Fiber Post root posts, by 3M ESPE, and light-curing composite core build-up materials.

The chemical composition of Adper Prompt/Adper Prompt L-Pop remained unchanged in comparison to 510(k) K040857. Performance data for Adper Prompt/Adper Prompt L-Pop in the indications for use already cleared by 510(k) are, therefore, not subject of this 510(k) submission. The data provided in this 510(k) submission shows that Adper Prompt/Adper Prompt L-Pop is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2006

Dr. Sabine Krischer
Regulatory Affairs Specialist
3M ESPE AG
ESPE Platz
Seefeld, Bavaria D-82229
GERMANY

Re: K060684
Trade/Device Names: Adper Prompt and Adper Prompt L-Pop
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: March 09, 2006
Received: March 15, 2006

Dear Dr. Krischer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K660684

Device Name: Adper Prompt

Indications For Use:

Bonding between dentin/enamel and composite filling materials
Bonding between dentin/enamel and compomer filling materials
Bonding mediator for fissure sealing
Desensitization of hypersensitive areas of teeth
Bonding between RelyX™ Fiber Post root posts and light-curing composite core build-up materials

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...ov. General Hosp...

K660684